

Patent claims

1. A bone replacement material comprising crystalline and X-ray amorphous phases, characterized in that

- a) according to ^{31}P -NMR measurements, said bone replacement material comprises Q_0 -groups of orthophosphate and Q_1 -groups of diphosphate, the orthophosphates or Q_0 -groups making up 70 to 99.9% by weight relative to the total phosphorus content of the finished material and the diphosphates or Q_1 -groups making up 0.1 to 30% by weight relative to the total phosphorus content of the finished material, and
- b) according to X-ray diffractometric measurements and relative to the total weight of the finished material, 30 to 99.9% by weight of a main crystal phase consisting of $\text{Ca}_2\text{K}_{1-x}\text{Na}_{1+x}(\text{PO}_4)_2$, where $x = 0.1$ to 0.9 , is contained in the bone replacement material and 0.1 to 20% by weight of a substance selected from the group consisting of $\text{Na}_2\text{CaP}_2\text{O}_7$, $\text{K}_2\text{CaP}_2\text{O}_7$, $\text{Ca}_2\text{P}_2\text{O}_7$ and mixtures thereof is contained as a secondary crystal phase, and
- c) the X-ray amorphous phases contained besides the main crystal phase jointly make up 0.1 to 70% by weight relative to the total weight of the finished material.

2. A bone replacement material comprising crystalline and X-ray amorphous phases, characterized in that

- a) according to ^{31}P -NMR measurements, the bone replacement material comprises Q_0 -groups of orthophosphate and Q_1 -groups of diphosphate, the orthophosphates or Q_0 -groups making up 70 to 99.9% by weight relative to the total phosphorus content of the finished material and the diphosphates or Q_1 -groups making up 0.1 to 30% by weight relative to the total phosphorus content of the finished material, and
- b) according to X-ray diffractometric measurements and relative to the total weight of the finished material, 30 to 99.9% by weight of a main crystal phase consisting of $\text{Ca}_2\text{K}_{1-x}\text{Na}_{1+x}(\text{PO}_4)_2$, where $x = 0.1$ to 0.9 , is contained in the bone replacement material and 0.1 to 20% by weight of a substance selected from the group consisting of $\text{Na}_2\text{CaP}_2\text{O}_7$, $\text{K}_2\text{CaP}_2\text{O}_7$, $\text{Ca}_2\text{P}_2\text{O}_7$ and mixtures thereof is contained as a secondary crystal phase, and

c) the X-ray amorphous phases contained besides the main crystal phase jointly make up 0.1 to 70% by weight relative to the total weight of the finished material,

obtainable by

mixing raw materials containing (in % by weight) 25-50 CaO, 1-20 Na₂O, 0.5-20 K₂O, 0-13 MgO and 0-10 SiO₂ and treating the aforesaid mixture with H₃PO₄ in an amount corresponding to 30-55 P₂O₅, SiO₂ or MgO or a mixture thereof making up at least 1% by weight, homogenizing and drying the mixture and subjecting it to a step-by-step thermal treatment lasting 1-2h at 350-450°C, 750-850°C and 950-1,050°C respectively, melting the mixture at between 1,550 and 1,650°C, holding it at the melting temperature for between 10 and 60 minutes and finally cooling the mixture in a spontaneous or temperature-controlled manner, grinding it, if necessary, and sintering it to obtain moulded bodies.

3. A bone replacement material according to Claim 1, wherein additionally one or more of the chain phosphates NaPO₃, KPO₃ and mixtures thereof are contained in an amount ranging between 0.1 and 10% by weight, which chain phosphates can be detected as Q₂-groups using ³¹P-NMR measurements.

4. A bone replacement material according to Claim 1, wherein x ranges between 0.2 and 0.9.

5. A bone replacement material according to Claim 1, wherein the secondary crystal phase contains a silicate phase corresponding to the SiO₂ content.

6. A bone replacement material according to Claim 1, wherein additionally magnesium in an amount ranging up to 10% by weight, calculated as MgO and relative to the weight of the finished material, is contained.

7. A bone replacement material according to Claim 1, wherein the orthophosphate phase represented by Q₀-groups makes up 75 to 99% by weight.

8. A bone replacement material according to Claim 7, wherein the orthophosphate phase represented by Q_0 -groups makes up 78 to 95% by weight.
9. A bone replacement material according to Claim 1, wherein the diphosphate phase represented by Q_1 -groups makes up 1 to 22% by weight, preferably 5 to 16% by weight.
10. A bone replacement material according to Claim 9, wherein the diphosphate phase represented by Q_1 -groups makes up 5 to 16% by weight.
11. A bone replacement material according to Claim 1, wherein the secondary crystal phase makes up 0.1 to 15% by weight.
12. A bone replacement material according to Claim 10, wherein the secondary crystal phase makes up 1 to 15% by weight.
13. A bone replacement material according to any of Claims 1 through 12, wherein the total solubility ranges between 30 and 500 μ g/mg, relative to the starting material if the test is carried out in 0.2M TRIS-HCl buffer solution at pH = 7.4, T = 37°C using a grain size fraction of 315-400 μ m, the duration of the test being 120h and the ratio of weighed-in sample to buffer solution being 50mg to 40ml.
14. A bone replacement material according to any of Claims 1 through 12, wherein the coefficient of expansion ranges between 12 and 18 x 10⁻⁶ K⁻¹, measured using a dilatometer.
15. A bone replacement material according to any of Claims 1 through 12, wherein the pH value of the surface changes by at least 0.7 units, preferably at least 1.5 units, towards the neutral point within the alkaline range if the material is stored in deionized water at room temperature for 72 hours or heated up to 60°C for 1 hour at a pressure of 1-3 bars and rinsed with deionized water.

16. A bone replacement material according to Claim 1, characterized in that said material is provided in combination with a metallic implant surface.

17. A bone replacement material according to Claim 1, wherein in the processed, finished state said material consists of (in % by weight):

30 to 55 P_2O_5 , 25 to 50 CaO, 1 to 20 Na_2O , 0.5 to 20 K_2O , 0 to 13 MgO

0 to 10 SiO_2 ; MgO or SiO_2 or a mixture thereof making up at least 1% by weight.

18. A bone replacement material according to Claim 17, wherein

MgO is in the range of 1-13 % by weight and SiO_2 is in the range of 0.5-5 % by weight;

MgO or SiO_2 or a mixture thereof making up at least 1% by weight.

19. A bone replacement material according to Claim 18, wherein said material contains 40 to 52 P_2O_5 , 28 to 33 CaO, 8.5 to 13 Na_2O , 9.5 to 15 K_2O , 1.5 to 3 MgO, 0.1 to 4 SiO_2 .

20. A bone replacement material according to Claim 1, wherein said material is provided in the form of granulated materials, ceramic bodies or ceramic sheets.

21. A method for manufacturing a bone replacement material comprising crystalline and X-ray amorphous phases according to Claim 1, characterized by mixing raw materials containing (in % by weight) 25-50 CaO, 1-20 Na_2O , 0.5-20 K_2O , 0-13 MgO and 0-10 SiO_2 and treating the aforesaid mixture with H_3PO_4 in an amount corresponding to 30-55 P_2O_5 , MgO or SiO_2 or a mixture thereof making up at least 1% by weight, homogenizing and drying the mixture and subjecting it to a step-by-step thermal treatment lasting 1-2h at 350-450°C, 750-850°C and 950-1,050°C respectively, melting the mixture at between 1,550 and 1,650°C, holding it at the melting temperature for between 10 and 60 minutes and finally cooling the mixture in a spontaneous or temperature-controlled manner, grinding it, if necessary, and sintering it to obtain moulded bodies.

22. A method according to Claim 21, wherein the raw materials are divided into two batches and melted separately, the first batch consisting of a melted glass comprising 73-78 SiO₂, 8-11 MgO, 8.5-10 Na₂O, 12-19 K₂O and 0-22 P₂O₅ (in % by weight), which glass is cooled, ground and added to the second batch, i.e. the X-ray amorphous-crystalline material of claim 21, in an amount ranging between 0.1 and 15% by weight and is sintered jointly with said second batch at 900-1,200°C to obtain moulded bodies.

23. A method according to Claim 21, wherein the mixture is melted at between 1,590 and 1,650°C.

24. A glass used as a sintering aid for resorbable materials containing calcium phosphates with the exception of β -tricalcium phosphate, which comprises the following chemical composition in % by weight:

SiO₂: 73-78, MgO: 8-11, Na₂O: 12-19, K₂O: 0-22, P₂O₅: 0-20.

25. A glass according to claim 24, which comprises the following chemical composition in % by weight:

SiO₂: 74-75; MgO: 8.5-10; Na₂O: 14.5-17; K₂O: 0-5; P₂O₅: 0-10.